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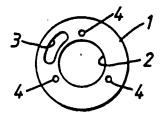
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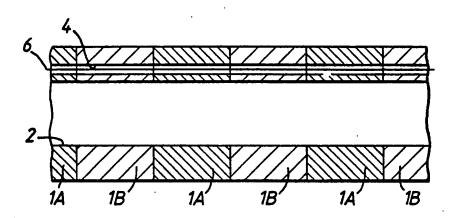
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(54) Title: SURGICAL CATHETERS





(57) Abstract

Surgical catheters (1) are composed of materials which are non-magnetic and opaque or translucent under Nuclear Magnetic Resonance examination, and preferably of segmented construction, with segments of highly opaque material (5) alternating with segments of less opaque material (6) to facilitate observation of the catheter by NMR image reconstruction.

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Surgical Catheters

This invention relates to operating catheters for use in surgical procedures.

Catheters in accordance with the invention are characterized in that they are composed of non-magnetic 5 materials which are opaque or translucent under Nuclear Magnetic Resonance (NMR) examination. Suitable materials may be hydron, or strongly paramagnetic materials such as gadolinium. The catheters are preferably of axially segmented construction, having segments of highly opaque 10 material alternating with segments of less opacity, so that the precise location of the catheter is readily apparent under NMR examination and visually at the distal end.

The catheters have, in each case, a main central lumen for the passage e.g. of optic fibres for laser surgery, or of drugs for perfusion into an organ or into a cancer, or of control elements for the manipulation of surgical instruments carried at the distal end of the catheter.

Additionally, further, small lumens may be provided through the length of the catheter wall, for the passage of guidance wires, or gas, or drugs.

The catheters are preferably coated, internally and externally, with thin layers of silicone rubber.

In each case, these catheters permit the conduct of

many operations and treatments which would otherwise be carried out under X-ray. When operations are of long duration or require repetitions, the patient is subjected to undesirable high exposure to X-ray radiation. The present catheters make it possible to conduct various procedures under NMR examination, which is non-invasive and not subject to the risks attendant upon exposure to radiation.

Some catheters in accordance with the invention and attachments for use therewith will now be described by way of example, with reference to the accompanying drawings, in which:

Fig. 1 is a diagrammatic cross-section of a catheter for use in cancer treatment;

Fig. 2 is an axial section, drawn to a larger scale, of the catheter of Fig. 1;

Fig. 3 is a perspective sketch of a second form of catheter, for use in laser surgery;

Fig. 4 is a perspective sketch of a catheter fitted 20 with a suturing device;

Fig. 5 is a front end view of a catheter fitted with a suturing device;

Figs. 6 and 7 are axial sections on the lines A', A' and A, B respectively, of Fig. 5; and

Fig. 8 is a front end view showing a suture needle in position.

The catheter 1 of Figs. 1 and 2 is composed of alternating annular segments 1A, 1B of materials which are highly opaque to NMR examination and less opaque,

30 respectively. The catheter has thin coatings of silicone rubber on its external surface and the internal surface of its main, central lumen 2. For the treatment of cancers, the lumen is charged with a quantity of embolising material which can be selectively discharged through the distal end of the catheter by a plunger (not shown)

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of NMR opaque material operable from the proximal end of the catheter.

A secondary lumen 3 formed through the wall of the catheter is charged with sclerosing materials. Three 5 equi-spaced fine lumens 4 also extend longitudinally through the catheter wall and form passages for high tensile guide wires 6. At the distal end, these wires are secured to the catheter wall, and at the proximal end they are coupled to a joystick or rollerball control which permits the wires to be selectively and individually tightened or relaxed so as to permit guidance of the distal end of the catheter.

In use of the catheter, embolising material can be selectively discharged into an artery supplying a tumour, or a vein draining it or both. The secondary lumen 3 may be used for the injection of sclerosing materials into the arterial system before embolisation.

Use of the catheter under NMR examination has the additional advantage that the efficacy of embolisation can be monitored while the treatment is under way by NMR examination of blood flow sequences.

In a modification the catheter may be of simple construction with just a main lumen, for use in the perfusion of tumour killing drugs which are too toxic to be adminstered systematically.

Fig. 3 illustrates a catheter specifically for use in laser treatment of coronary atheroma. catheter is of generally similar construction to that of Figs. 1 and 2, but its main lumen carries a sheathed bundle of optic fibres for transmitting laser light to the site. The sheath 7 may incorporate additional fine lumens 8 for the perfusion of prostacyclin or other platelet controlling agents, and a dye for staining atheromous material to a colour which makes it sus-35 ceptible to laser light. These lumens may, of course,

alternatively be incorporated through the wall of the catheter.

Further fine lumens corresponding to the lumens 4 of Fig. 1, are provided for controlling wires, as before, 5 for the supply of pressurised gas to a small inflatable sac or sacs 9 carried near the distal end of the catheter. Preferably, these sacs are distributed about the circumference of the catheter. They are individually inflatable (or collapsible) so as to press against the artery wall and thereby permit fairly precise positioning and orientation of the distal end of the catheter and thus of the laser light emitted from it. The sacs may also be abruptly inflated together to disrupt an occlusion.

In a further group of modified catheters, adapted

15 for surgical procedures such as suturing, boring, biopsy
sampling and guiding pacemaker wires into position, the
catheters are again of the same basic construction, but
no lumens are provided for the passage of drugs or other
agents to the site. The catheter again incorporates

20 lumens for control wires and the central lumen is employed
for the mechanical control elements to operate tool
pieces mounted at the distal end of the catheter.

Fig. 4 illustrates such a catheter fitted with a suturing device. The central lumen houses a flexible,

25 torque-transmitting control cable attached to a suture driver 11 of tubular form, having bayonet slots 12 for locating the cross tang 13 of a wire suture of helically spiralling form, the helix becoming progressively tighter in a direction away from its pointed leading end.

30 The tang is engaged across the inner ends of the bayonet slots. The suture is applied by pressing it against the site to be stitched and then rotating it, by operation of the control cable, causing the pointed end to penetrate the septal wall (or other muscle or material to be stitched) and with continual rotation the suture is

wound progressively into the muscle and concomitantly drawn out of the bayonet slot.

Instead of the suturing device described and illustrated, the same catheter can be fitted with other tool pieces specially adapted for boring, removal of samples for biopsy or the guidance of pacemaker wires.

The catheter shown in Figs. 5 to 8 is for stitching with a filamentary suture. In this case, the catheter is provided with a small central lumen to receive the suture filament 12 and two further lumens housing con-10 trol cables 13. Coupled to the distal end of the catheter is a suturing device comprising a generally cup-shaped housing 14 having two through holes in its front wall in which are mounted respective grippers 16. The holes are angled away from each other, and they 15 taper forwardly. The grippers 16 are of a springy material and each has a pair of jaws which are forced together when the gripper is pushed forwardly in its tapered hole. When partially retracted, the jaws spring 20 apart again. The grippers are of generally circular cross-section and are keyed against rotation in their holes. At their rear ends, the grippers are releasably connected as by ball and socket joints 17 to their respective control cables 13.

Initially, and as shown as Fig. 8, the grippers are both closed against a suture needle 18 attached to the suture filament. The catheter is inserted through a blood vessel to the site to be repaired and suturing is effected by rotation of the head and alternate operation of the grippers to push and pull the needle through the muscle or other tissue to be stitched. The head may be rotatable by a control cable or it may be rotatable within a surrounding sheath extending substantially the full length of the catheter.

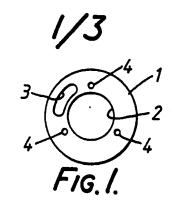
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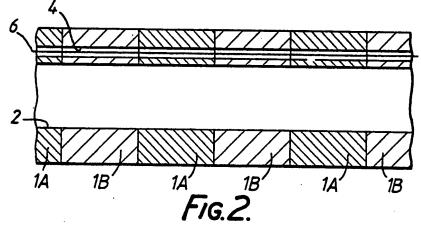
CLAIMS:

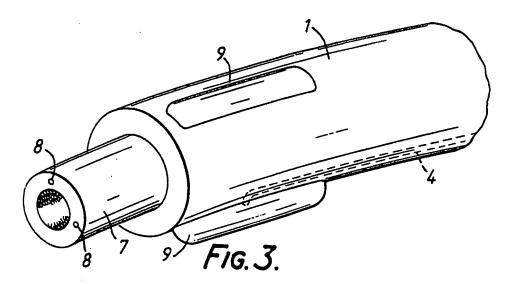
- 1. A surgical catheter composed of a non-magnetic material (or materials) which is (or are) opaque or translucent under Nuclear Magnetic Resonance (NMR) examination.
- 2. A catheter according to claim 1, characterized in that the catheter is of axially segmented construction, having segments (1A) of highly opaque material alternating with segments (1B) of less opacity.
 - A catheter according to claim 1 or 2, having
 a central lumen, characterized in that further lumens
 (4) are provided through the length of the catheter wall.
 - 4. A catheter according to claim 3, characterized in that a plurality of said further lumens (4) are distributed circumferentially about the catheter wall and that guidance wires (6) are housed in the said further lumens (4) and are secured to the wall of the catheter at its distal end and at the proximal end are coupled to a control mechanism for selective tensioning of the wires to facilitate radial guidance of the distal end of the catheter.
- 5. A catheter according to claim 3, characterized in that the said further lumens (4) form passages for the supply of pressurized fluid to selectively inflatable sacs (9) distributed about the exterior of the catheter wall at the distal end thereof.
- 6. A catheter according to any preceding claim, characterized in that the central lumen (2) of the catheter houses a bundle of optical fibres for the transmission of

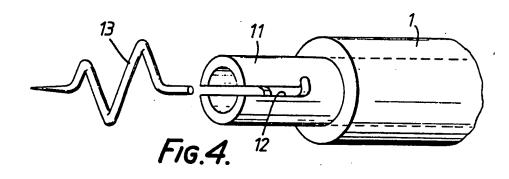
laser light to the distal end of the catheter.

- 7. A catheter according to any one of claims 1 to 5, characterized in that the catheter carries a rotatable suturing device (11;14,16) at its distal end.
- 8. A catheter according to claim 7, characterized in that the suturing device comprises a generally cupshaped housing (14) and a pair of grippers (16) each having a pair of jaws projecting through the front wall of the housing and connected at their rear, inner ends to respective control elements by which the jaws of the grippers can be alternately opened and closed for manipulation of a curved suturing needle.

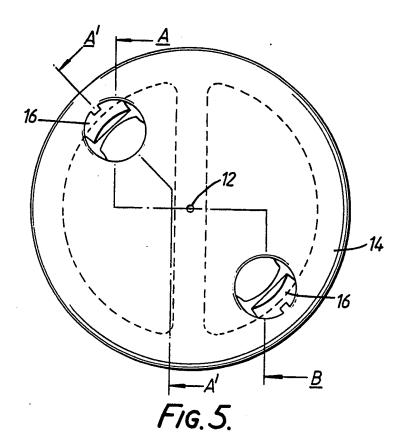


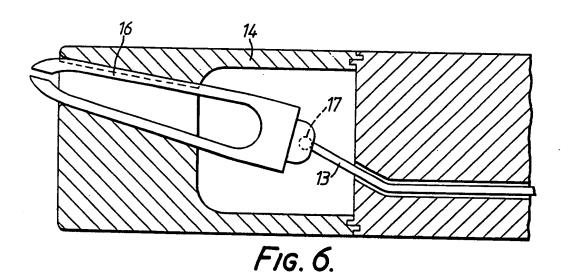


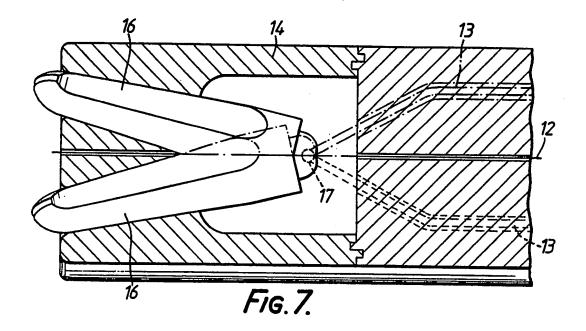


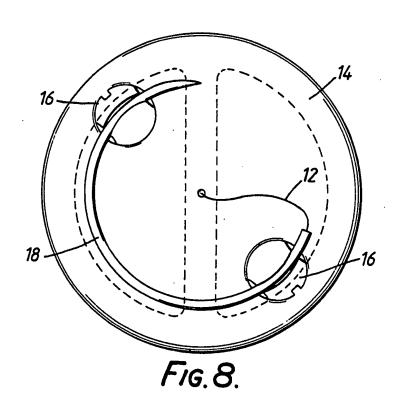


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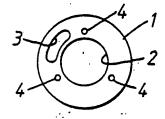
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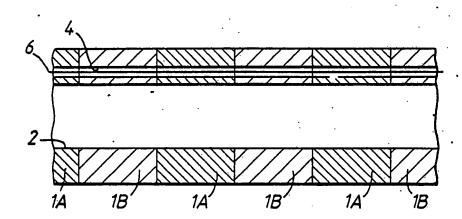
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

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INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 87/00014

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *						
According to International Patent Classification (IPC) or to both National Classification and IPC						
IPC4:	A 61	M 25/00; G 01 N 24/0)2			
II. FIELDS SEARCHED						
Classificat	ion System		nentation Searched 7			
	Jon System	1	Classification Symbols	· · ·		
IPC ⁴		A 61 M; A 61 B; G 0	1 N			
Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched						
	-					
III. DOCE	UMENTS	CONSIDERED TO BE RELEVANT				
Category *	Cita	tion of Document, 11 with indication, where as	ppropriate, of the relevant passages 12	Relevant to Claim No. 13		
X	EP,	A, 0165742 (VARIAN A	SSOCIATES)			
		27 December 1985, se page 2, line 20; cla	e page 1. line 27 -	1,3,6		
Y				2,4,5		
Y	US,	A, 3847157 (CAILLOUE 12 November 1974, se lines 46-61	TTE et al.) e column 1,	2		
Y	us,	4,5				
P,X	WO, A, 86/01093 (BERKE) 27 February 1986, see page 5, line 14 - page 6, line 23			1,3,4		
A	US, A, 3470876 (BARCHILON) 7 October 1969					
A	DE,	A, 2820239 (OLYMPUS of November 1978	OPTICAL)			
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date invention "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means: "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date of priority date and not in conflict, with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "A" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "A" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.						
Date of the Actual Completion of the International Search 7th April 1987 Date of Mailing of this International Search Report 14 JUL 1987						
EUROPEAN PATENT OFFICE Signature of Authorized Office M. VAN MOL						

FURTHER INFORMA	TION CONTINUED FROM THE SECOND SHEET
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v. OBSERVATION	S WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE!
This international search	report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:
	because they relate to subject matter not required to be searched by this Authority, namely:
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Claim numbers	because they relate to parts of the international application that do not comply with the prescribed require-
ments to such an e	extent that no meaningful international search can be carried out, specifically:
Claim numbers	because they are dependent claims and are not drafted in accordance with the second and third sentences of
PCT Rule:6.4(8).	
I. OBSERVATION	S WHERE UNITY OF INVENTION IS LACKING 2
<u> </u>	
•	ing Authority found multiple inventions in this international application as follows:
- claims 1-6	
•	comprising guide wires, inflatable sacs and optical fibres
- claime 1.7	8: Surgical catheter carrying a rotatable suturing device
	tional search fees were timely paid by the applicant, this international search report covers all searchable claims
of the international	
	international application for which fees were paid, specifically claims:
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No required addition	nal search fees were timely paid by the applicant. Consequently, this international search report is restricted to
	entioned in the claims; it is covered by claim numbers:
,	1-6.
	the sould be assented without affine livelifying an additional for the International Countries Authority and
As all searchable clain invite payment of an	lims could be searched without effort justifying an additional fee, the International Searching Authority did not by additional fee.
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	h fees were accompanied by applicant's protest.
No protest accompa	inled the payment of additional search less.

INTERNATIONAL APPLICATION NO.

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 25/06/87

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Patent document cited in search report	Publication date	Patent f member	-	Publication date
EP-A- 0165742	27/12/85	JP-A- US-A-	61013974 4572198	22/01/86 25/02/86
US-A- 3847157	12/11/74 ·	None		
US-A- 3058473		None		
WO-A- 8601093	27/02/86	EP-A- JP-T-	0191828 62500048	27/08/86 08/01/87
US-A- 3470876	07/10/69	None		
DE-A- 2820239	16/11/78	JP-A-	53139390	05/12/78